

REMARKS

Summary of the Invention

The invention features isolated nucleic acids, or subfragments thereof, that have RNA binding protein (RBP) binding activity or that regulate the functionality of the nucleic acid.

Restriction Requirement and Species Election

Applicants affirm their provisional election made without traverse to prosecute the invention of Group I, claims 1-3. Accordingly, claims 4-11 have been canceled as being drawn to a non-elected invention. Applicants also affirm the provisional election of the disclosed species SEQ ID NO: 20 for prosecution of the elected claims.

Support for the Amendments

Support for amended claims 1 and 2 is found in the specification at page 11, line 3, to page 12, line 26, and at page 8, lines 4-10. Support for new claims 12-31 is found in the specification at page 10, line 7, to page 11, line 26. In addition, the specification has been amended to correct a typographical error. The error is regretted. No new matter is added by the amendment.

Summary of the Office Action

Claims 1-3 were examined in this case. Claim 1 is objected to on the ground that the identified sequences are not properly referred to. Claims 1 and 3 are rejected under 35 U.S.C. § 101. Claims 1-3 stand rejected under 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 102(a), and claims 1 and 2 are rejected under 35 U.S.C. § 112, second paragraph. These rejections are addressed below in the order in which they appear in the Office Action.

Rejections under 35 U.S.C. § 101

Claims 1 and 3 stand rejected under 35 U.S.C. § 101, based on the statement in the Office Action that the claimed invention reads on products of nature. In response to this rejection, Applicants have amended claim 1 to recite an “isolated” nucleic acid. A nucleic acid that had been amplified according to the methods of the invention has been isolated, has seen the hand of man in its preparation, and is not a product of nature. In addition, as claim 3 depends from claim 1, it no longer reads on a product of nature. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-3 are rejected under 35 U.S.C. § 112, first paragraph, on the ground that they contain subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed has possession of the claimed invention. Specifically, the Examiner states that there is no disclosure in the specification as to which portions of SEQ ID NOS: 1-20 bind RNA binding proteins, and no relevant example of where one of the identified sequences has been used to bind an RNA binding protein or to alter an mRNA's functional characteristics. The Examiner concludes that one cannot predict, based on the teachings of the specification or the prior art, what changes in one of SEQ ID NOS: 1-20 will allow binding of an RNA binding protein or allow regulation of an RNA's functional characteristics, and that one of skill in the art would not be able to visualize a representative number of all of the nucleic acids encompassed by claims 1-3. This rejection is addressed as follows.

In response to this rejection, Applicants point out that the specification, at pages 10-12, teaches that the nucleic acid sequences of SEQ ID NOS: 1-20 were tested and confirmed to have RBP binding activity. Accordingly, Applicants assert that any heterologous nucleic acid sequence, as recited in claim 1, that contains the sequence of any one of SEQ ID NOS: 1-20 also has RBP binding activity.

Applicants submit that claims 1-3, as amended herewith, adhere to the interim guidelines on written description. The specification clearly states that a subfragment nucleic acid of the present invention comprising the nucleic acid of any of SEQ ID NOS: 1-20 that has been shortened at the 5' or 3' end, or internally deleted, and has RBP binding

activity or regulates the functionality of the nucleic acid are essential to the operation of the claimed invention. Although methods for producing a subfragment nucleic acid of the invention and for assaying the subfragment for RBP binding activity or the ability to regulate the functionality of the nucleic acid are conventional in the art, the specification provides procedures for generating such subfragments. For example, as described in the specification at page 12, subfragment nucleic acids of SEQ ID NOS: 1-20 may be obtained by subjecting any one of SEQ ID NOS: 1-20 to restriction mapping or PCR techniques to generate smaller fragments of SEQ ID NOS: 1-20, where one would know the exact sequence of the smaller fragment. Assays to determine if these subfragments have the claimed RBP binding activity or the ability to regulate RNA functionality is also described in the specification at page 11-12.

The specification also clearly describes a number of distinguishing identifying characteristics of a nucleic acid subfragment, including the functional characteristics of the subfragments, methods of making the subfragments, and the parent sequence from which the subfragments are derived. Applicants submit that based on these factors, in combination with the level of skill and the knowledge in the art, one skilled in the art would conclude that Applicants were in possession of the invention as recited in claims 1-3. Thus, Applicants respectfully request that the rejection be withdrawn.

Applicants further submit that new claims 12-31, reciting nucleic acids or subfragment nucleic acids comprising individual sequence identification numbers, also

meet the written description requirement, for the reasons discussed above.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-3 are rejected under 35 U.S.C. § 112, second paragraph, on the ground that they are indefinite for failing to point out and distinctly claim the subject matter that Applicants regard as the invention. Each of the several points raised by the Examiner is now addressed individually below.

The Examiner states that claim 1 is vague and indefinite in the metes and bounds of the phrase “..or a subfragment nucleic acid sequence derived from any one of the sequences of SEQ ID NOS: 1-20...,” specifically stating that the claim is unclear as to what constitutes a derivative of one of the identified nucleic acid sequences. In response to this basis for the rejection, Applicants point out that claim 1 has been amended to recite that a subfragment comprises the “nucleic acid that has been shortened at the 5' or 3' end, or internally deleted.” Claim 1 now clearly states what a subfragment derived from any one of the sequence of SEQ ID NOS: 1-20 is. Accordingly, this basis for the rejection should be withdrawn.

The Examiner also states that claim 1 is vague and indefinite in that there is no antecedent basis for the term “said mRNA.” Applicants note that claim 1 has been amended such that the phrase “said mRNA” is not recited. This aspect of the rejection may now be withdrawn.

Claim 1 is also rejected based on the assertion by the Examiner that it is not clear whether the term “said sequence” having RBP binding activity or regulating the functionality of the RNA refers to the first nucleic acid sequence or to the nucleic acid sequence derived from one of SEQ ID NOS: 1-20. Applicants point out that claim 1 has been amended herewith to recite that “said sequence” has been replaced by “an mRNA molecule comprising said nucleic acid, or an mRNA comprising said subfragment nucleic acid.” Applicants submit that amended claim 1 is now unambiguous in its recitation of which nucleic acid has binding activity or regulates the function of the nucleic acid.

Accordingly, this basis for the rejection may now be withdrawn.

Claims 1 also stands rejected based on the assertion by the Examiner that the phrase “wherein an mRNA molecule comprising said sequence has RNA binding (RBP) binding activity or regulates the functionality of said mRNA” is unclear. The Examiner suggested amending the language of claim 1 to clearly link the presence of one of the nucleic acid sequences of SEQ ID NOS: 1-20 in an mRNA molecule to its ability to bind an RNA-binding protein and to directly link the presence of such a sequence to the functional characteristics of the RNA molecule.

In response to this aspect of the rejection, Applicants note that claim 1 has been amended to clearly recite that the an mRNA molecule comprising said nucleic acid or an mRNA molecule comprising said subfragment nucleic acid has RBP binding activity or that it regulates the functionality of the nucleic acid. Applicants submit that amended

claim 1 now clearly recites that the nucleic acids or subfragment nucleic acids of the invention are directly linked to the recited RBP binding activity or nucleic acid functionality. This basis for the rejection may now be withdrawn.

Claim 2 is rejected on the ground that the term “optimized” is unclear. In response, Applicants note that claim 2 has been amended herewith to recite the functional characteristics of an optimized subfragment nucleic acid. Applicants assert that the term “optimized” is now clearly defined, and respectfully request that this portion of the rejection be withdrawn.

Applicants further assert that new claims 12-31, which depend from claim 1 and recite nucleic acids or subfragment nucleic acids comprising individual sequence identification numbers, also point out and distinctly claim the subject matter Applicants regard as the invention.

In light of the above comments, Applicants submit that the rejection of claims 1-3 under 35 U.S.C. § 112, second paragraph, has been overcome. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 102(a)

Claims 1-3 stand rejected under 35 U.S.C. § 102(a) based on the assertion in the Office Action that the claims are anticipated by Nagle et al. (Nature 398:148-152, 1999, hereafter Nagle) or Gunn et al. (Nature 398:152-156, 1999, hereafter Gunn) and the

search report for SEQ ID NO: 20 (GenBank Accession Nos. AF116897 and AF120318).

This rejection is addressed as follows.

The publication of Nagle discloses the cloning of the *mahogany* gene, the *mahogany* nucleic acid sequence (submitted as GenBank Accession Number: AF116897), including UTR sequence, and predicted protein sequence. Gunn discloses the cloning of the gene responsible for the *mahogany* mutation (which they name *Mgca*), the *Mgca* nucleic acid sequence (submitted as GenBank Accession Numbers: AF120317 and AF120318), including UTR sequence, as well as its predicted protein sequence.

As it relates to the cited art, amended claims 1-3 recite an isolated nucleic acid comprising any one of the sequences of SEQ ID NOS: 1-20 that is operatively linked to a heterologous sequence. Neither Nagle nor Gunn teach the use of the *mahogany* UTR (SEQ ID NO: 20) operatively linked to a heterologous nucleic acid sequence, and thus neither piece of cited art (including their associated GenBank Accession Numbers) anticipates claims 1-3, as now amended. Accordingly, Applicants respectfully request that the rejection be withdrawn.

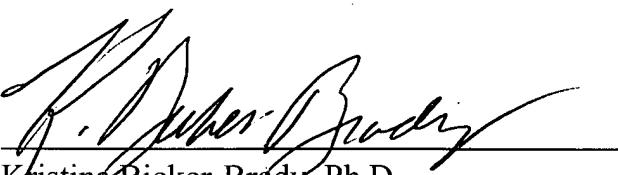
CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is requested.

Enclosed is a petition to extend the period for replying for three months, to and including November 23, 2000. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: November 17, 2000



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